

Reply on August 27, 2012 (D.I. 71). NAI has now filed the Notice, again not permitted by the Management Order. Because NAI's Notice was not permitted by the Management Order, it should not be considered by this Court. These multiple improper filings are nothing more than a desperate attempt by NAI to save its patents from a finding of invalidity.

In the event that this Court will consider NAI's Notice, Woodbolt files this Response.

Validity of Dietary Supplement Composition Patents

NAI argues in its Notice that beta-alanine, in the context of its two patents, is "man-made". However, NAI has failed to point to any wording in its specification or claims that the scope of its patents is limited to "man-made" beta-alanine. In fact, the specifications of both patents show quite the opposite -- in Example 2 of the patent specifications, NAI describes beta-alanine in a broth made from chicken and therefore naturally-occurring, and being administered as a dietary supplement.

There is nothing in the claims of either of NAI's patents which requires that beta-alanine be "man-made". Even if the patents did require use of "man-made" beta-alanine, NAI has not demonstrated, nor could it so demonstrate, that "man-made" beta-alanine is any different from naturally-occurring beta-alanine. Beta-alanine, whether naturally-occurring or man-made, is still structurally the same beta-alanine.

The examples cited by NAI of "dietary supplement" patents upheld by the courts are easily distinguished. These patents were for "compositions" which were not naturally occurring and which were not disclosed in the prior art and so their validity was upheld. However, here NAI's beta-alanine "composition" is naturally-occurring and has been widely disclosed in the prior art.

In NAI's case of *Creative Compounds, LLC v. Starmark Laboratories*, 651 F. 3d 1303 (Fed. Cir. 2011), the claims of two patents were directed to *new* creatine compositions, including a creatine salt and a dicreatine malate compound, both of which were not found in nature and were not disclosed in the prior art.

In *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, 464 F. 3d 1339 (Fed. Cir. 2006), the patent claim recited a carotenoid composition of substantially pure lutein crystals which did not contain any toxic chemicals, in a form which did not exist in nature and was not disclosed in the prior art.

In *Everett Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*, 573 F. Supp. 2d 855 (D.N.J. 2008), the patent claimed a novel prenatal nutritional supplement containing a new combination of certain amounts of vitamins and minerals which did not exist in nature and was not disclosed in the prior art.

In *ThermoLife Int'l, LLC v. Sechel Holdings, Inc.*, 2012 U.S. Dist. LEXIS 42419 (D. Ariz. Mar. 28, 2012), the patent claimed a novel compound of an amino acid and a nitrate or nitrite which was not naturally-occurring and was not disclosed in the prior art.

While these four cases upheld patentability because the compositions were not naturally-occurring and were not disclosed in the prior art, NAI's '381 patent merely recites a composition of beta-alanine, a naturally-occurring amino acid. Beta-alanine has been widely disclosed and used in the prior art.

New Use of Old Compositions

NAI cites *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 347 F.3d 1367, 1372 (Fed. Cir. 2003) and *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001) for the proposition that a novel method of use of a known compound is patentable.

These cases do not help NAI. In *Merck*, the validity of therapeutic treatment claims for a known composition was upheld because the new claimed treatment wasn't disclosed in the prior art. In *Rapoport*, the validity of claims for a new use for a known composition was upheld because the prior art didn't disclose the new use, either explicitly or inherently.

In the present case, NAI has not discovered a new method of using a known compound. The use of beta-alanine as a dietary supplement to increase the level of carnosine in muscle tissue was known from prior art (*e.g.*, Asatoor, Gardner, Hama), and the beneficial effects of carnosine, namely delaying or avoiding the onset of muscle fatigue, were well-known in the prior art (*e.g.*, Setra; admissions by NAI's inventors in the "Background" sections of the '381 and '422 patents).

NAI also cites *Pfizer Inc. v. Teva Pharms. USA Inc.*, 803 F. Supp. 2d 409 (E.D. Va. 2011) for the proposition that a new use of a known composition is patentable. There the compound sildenafil citrate had been used to treat angina, hypertension, heart failure and atherosclerosis, but had not been used to treat erectile dysfunction. So Pfizer was able to obtain a new patent on the use of the composition for treating erectile dysfunction.

Here, the prior art, indeed multiple references, disclosed every aspect of the invention, *i.e.*, the use of beta-alanine to increase the level of carnosine in the muscles and thereby delay the onset of fatigue, the very effect NAI asserts it "discovered" in its '422 patent.

How Beta-Alanine Works

In its description of how beta-alanine works, NAI has simply provided a description of what the human body has been doing naturally for many years when beta-alanine-containing foods are consumed.

NAI argues that its inventors “discovered” that ingesting the single amino acid beta-alanine in amounts over a period of time delays the onset of muscle fatigue because hydronium ions are absorbed by the carnosine formed in the muscle tissue. But the human body has been doing this naturally for as long as humans have been consuming beta-alanine-containing food such as chicken. Thus the inventors didn’t discover anything, but merely observed a well-known natural process. Moreover, they weren’t even the first to make this observation, as the same observation had been made previously by others such as Asatoor. Patents are not granted for “observations” of natural phenomena (even to first “observers”), or for administering naturally-occurring compositions to obtain the very same results other human subjects have long been experiencing.

NAI argues that sufficient beta-alanine cannot be obtained from a normal diet, and gives examples of the huge quantities of McDonald’s Big Macs it says are necessary to obtain 3,200 mg of beta-alanine. But its patents don’t mention *any* source of beta-alanine other than chicken broth and a “capsule” containing beta-alanine. It is telling that NAI does not mention the example of beta-alanine-rich chicken broth, as described in its patents, which humans have been consuming for years, and which provide beta-alanine to achieve the result NAI argues is needed.

While NAI now alleges that its claims require certain dose amounts of beta-alanine and multiple dosages over prolonged periods, nowhere do the claims state or require such certain dose amounts or multiple dosages, and the patent specifications do not identify any critical minimum dosage or frequency to achieve what NAI *now* alleges is the critical beneficial result. Further, because the prior art teaches beneficial results of certain dose amounts and one or two dosages of beta-alanine, it is only logical and obvious to try to increase dose amounts and frequency to obtain more and perhaps better results, as one would expect that if some is good,

more would be better. NAI's newly-hatched theory of its "discovery" is just a desperate attempt to somehow rescue its claims from invalidity in view of the prior art.

In sum, NAI's Notice is another desperate and failed attempt to repackage its "invention" to avoid the inevitable invalidation of its patents in view of novelty-destroying prior art.

Respectfully submitted,

OF COUNSEL:

/s/ Barry Evans

Peter J. Phillips (*pro hac vice*)
Barry Evans (*pro hac vice*)
LUCAS & MERCANTI, LLP
475 Park Avenue South, 15th Floor
New York, NY 10016
(212) 661-8000
pPhillips@lmiplaw.com
bevans@lmiplaw.com

Dated: September 27, 2012

Jayme Partridge
Paul Dyson
Fulbright & Jaworski
1301 McKinney, Suite 5100
Houston, Texas 77010
(713) 651-5151
jpartridge@fulbright.com
pdyson@fulbright.com

*Attorneys for Defendant Woodbolt
Distribution, LLC*

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS**

CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2012, I caused the foregoing document to be electronically filed with the Clerk of Court using CM/ECF, which will send notification of such filing to all counsel of record.

/Michael Scarpati/